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LETTER TO FDA
Dockets Management Branch (HFA-305)
Food and Drug Administration
ATTN: Docket #98N-0044
c/o Michael Friedman, M.D.
Lead Deputy Commissioner
5630 Fishers Lane, Room 1061
Rockville, MD 20857-0001

Dear Dr. Friedman,

I am writing to notify you that FDA's proposed rulemaking on structure/function claims, 21 CFR Part 101/Docket#98N-0044, is totally unacceptable to me as an American consumer of dietary supplements. Any final rule must reflect the true meaning and intent, mandated by Congress, of the Dietary Supplement Health and Education Act (DSHEA) of 1994. I support FDA's effort to fully implement DSHEA as intended by Congress, however I strongly object to the proposed regulations which:

- 1.) limit my access to (scientific) information about dietary supplements and health, and
- 2.) redefine disease restricting my ability to focus on preventive care and wellness.

It is extremely important to preserve Section 6 of DSHEA to allow for a robust flow of valuable health information in the marketplace.

I want free access to available information about dietary supplements and health, and I want FDA to withdraw its proposal to redefine disease in a way that limits such health information.

DSHEA allows products to make structure/function claims on the product labels. Redefining disease to nullify that part of DSHEA must be withdrawn.

If this is true, that you are planning to limit or deny access to information about dietary supplements and health, I must strongly object. Also, if you are planning to classify menopause, ageing, PMS & Pregnancy as "diseases," you must reconsider. Medical dictionaries define disease as "abnormal" pathological conditions. Surely even government workers do not view those conditions as abnormal. I hope this is all a joke!

Sincerely,
Nola Higley
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